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In re application of:

Guinan *et al.*

Appl. No.: 09/881,080

Filed: June 12, 2001

For: **Tip Seal Tip Attach**

Confirmation No.: 8025

Art. Unit: 3743

Examiner: Odland, Kathryn P.

Atty. Docket: P936US (1737.2900000)

Declaration Under 37 C.F.R. § 1.131

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned, Terry Guinan, John Connolly, Pat Duane, Donagh O'Shaughnessy, and Michael Bannon, declare and state that,

1. We are the inventors of the above-captioned application, U.S. Appl. No. 09/881,080, filed June 12, 2001.
2. Prior to December 21, 2000, we, the inventors, had completed our invention in the United States, as described and claimed in the subject application, as evidenced by the following.
3. Exhibit A is pages 52-60 of a laboratory notebook of Ronan Rogers in which tests for "B3 Concepts Development Builds" were recorded. In particular, four (4) design concepts were built (at least partially) and tested. Designs "B" and "D" are as described in the claims of the above-referenced application, wherein the guidewire tubular member includes a proximal segment formed of a first material having a first flexibility bonded to a distal segment formed of a second material different from the first material and having a second flexibility, wherein a bond joins the distal end of the balloon to both the proximal and distal segments of the guidewire tubular member.

4. As shown and described on page 53 and FIG. 2.0, Design "B" included a stiff polyethylene ("PE") inner shaft with a PEBAX 6333 co-extruded tip, wherein the PE inner shaft and the tip were bonded end-to-end and to the balloon distal neck.

5. Similarly, as shown and described on page 54 and FIG. 4, Design "D" was similar to Design "B" except that a PEBAX 7233 inner shaft replaced the PE inner shaft. The tip was PEBAX 6333 and the balloon distal neck, PEBAX 7233 inner shaft and PEBAX 6333 tip were bonded together.

6. As shown on page 58, an animal trial was conducted using Design "D" and it worked for its intended purpose.

7. The redacted dates of Exhibit A are prior to December 12, 2000.

As the persons signing below, we hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issue thereupon.

17th August, 2004
Date

Terry Guinan
Terry Guinan

6/8/04
Date

John Connolly
John Connolly

17th Aug 2004
Date

Pat Duane
Pat Duane

16th August, 2004
Date

Donagh O'Shaughnessy
Donagh O'Shaughnessy

17th August, 2004
Date

Michael Bannon
Michael Bannon

Background

Background
Four major stent delivery designs were devised with the emphasis placed on producing smooth trackability. The general guide line was to reduce the stiffness transitions along the distal section of the system, specifically the areas of localized "low" stiffness immediately proximal and distal to the stent (see P36). These particular areas may result in potential kinking points.

Designs A, B, C & D were fabricated. ie A, B, C & D. Designs A & D were used in an acute animal trial for the BeStent 3 Coronary Stent System on the 3rd July 2000 and designs A, B & C were bench tested using the 90° wire track test to correlate with the animal trial results. The four designs were as follows:-

Design A.

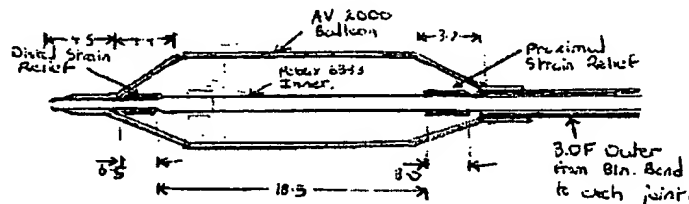


Fig 1 Design A

Design A (see RT 82 0006095) uses the AV 2000 balloon and the more flexible Pebax 6333 inner

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It has a 3.0 F outer from the balloon bond to the exchange joint and a distal and proximal strain relief ^{see 11/1/99} welded to the inner under the proximal and distal balloon cones (see fig 1). The distal strain relief is a 3.5 mm ^{long} section of AV100 distal balloon neck, while the proximal strain relief is a section of Culyon Exact proximal balloon neck.

Design B

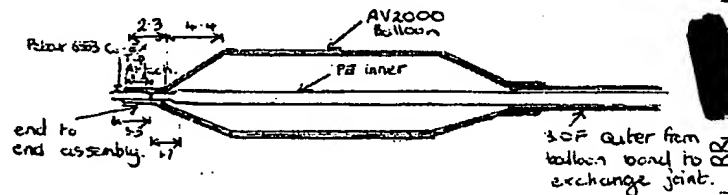


Fig 2.0 Design B

Design B (see RT B2 0006096) has the same balloon and outer as Design A (this design feature is common to all the designs). It has a stiff PE inner that has a Pebax 6333 C-Ex tip attach under the distal balloon neck. The tip and inner are assembled end to end and welded together, and to the balloon, ^{see 11/1/99} during tip seal.

Design C

Design C ^{see 11/1/99} is similar to Design B ^{see 11/1/99} except the Pebax 6333 is joined to the PE inner midway between the proximal and distal cones.

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Ronan Rogers.

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to eliminate the exchange joints on Designs B + C due to the presence of the PE. Therefore designs B + C ^{are} ~~there~~ only contain the distal sections. Designs A + D are complete builds.

Results

Design A

Animal Trial:

Trackability + Pushability + Pull back evaluation —
 acted better than all the prototypes ^{or competitors} used in
 the trial for track and pull back into the
 guide, with equivalent pushability.

Side Branch Access evaluation — the best of
 all the systems tried — accessed the side branch
 quite easily.

Bench Test.

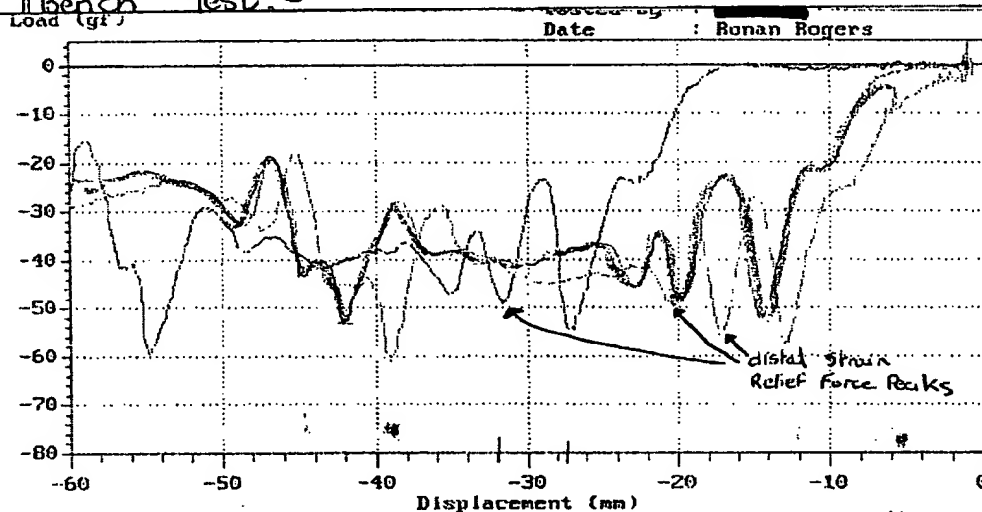


Fig. 50 Design A Wire Track Results.

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Ronan Rogers

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TITLE B3 Concept Development Builds Project No. 83

From Fig 5 it can be seen the distal strain relief is very prominent and has a very definite force peak. The proximal strain is not very obvious, but there is some evidence to suggest the trough between the proximal end of the stent and the balloon bond has been shortened (see P28). See Table 1 for tubulated results.

Design B

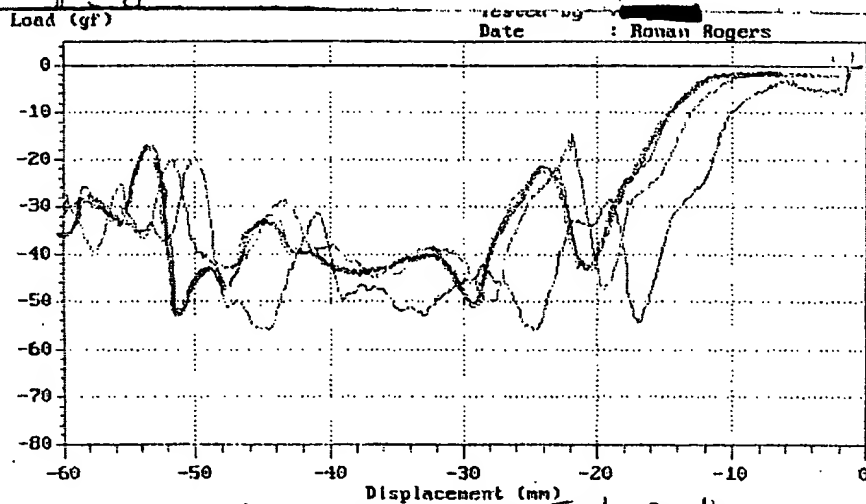


Fig 6.0 Design B Wire Track Results.

Animal Trial : — N/A.

Bench Test.

Design B has a slightly smoother track profile, especially towards the distal proximal

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title B3 Concept Development

Project No. B3

end This is due to the stiff PE inner, but the distal trough is very evident while a kinking effect in the PE was noticed proximal to balloon bond, during testing.

Design C

Animal Trial - N/A

Bench Test

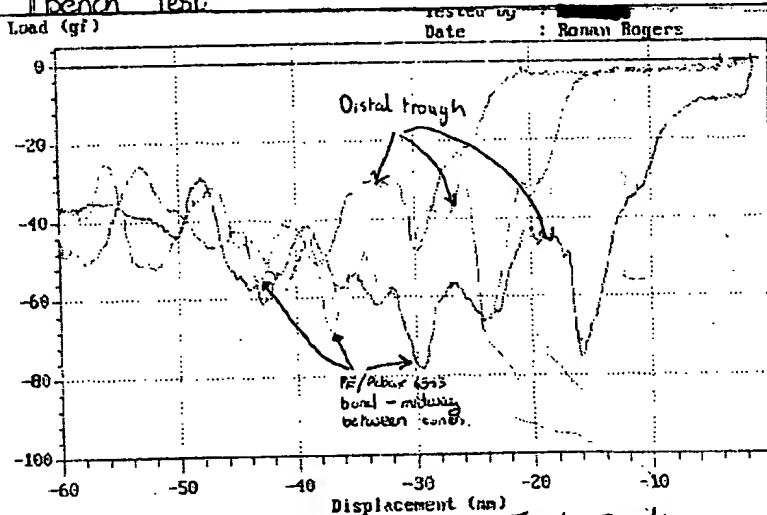


Fig. 7.0 Design C Wire Track Results.

From Fig 7.0 the two most striking features are the large width of the distal trough and the distinctive peak caused by the bond between the two inners midway.

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between the balloon cones. This obviously highlights the stiffness that can be achieved by welding materials on the inner and how the PE does not produce the required stiffness to minimise/affect the distal trough.

Design D

Aiming Trial - system trackability + pushability were noted equivalent to the competitor but there was resistance on pullback into the guide.

Bench Test - N/A

Tetra + Velocity
Bench Test

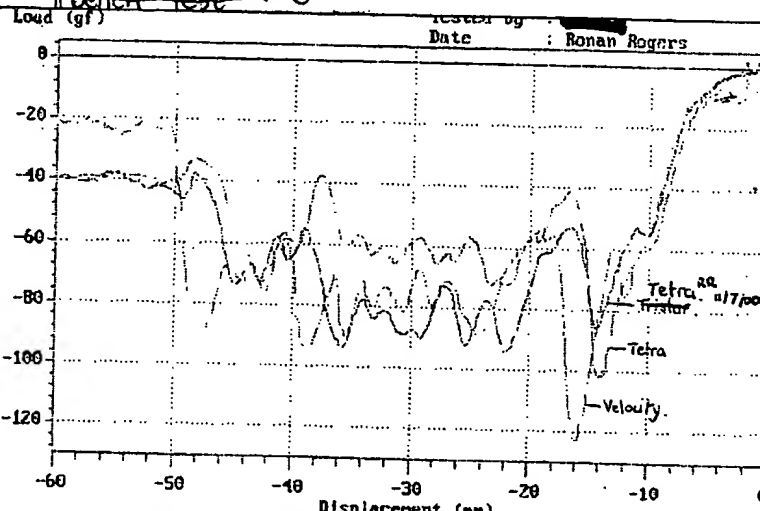


Fig 8.0 Tetra + Velocity Wire Track Results.

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Animal Trial

Tetra - trackability worse than prototypes - more resistance on pullback into guide. It had equivalent side branch access.

Velocity - much worse than all previous prototypes - more resistance on pullback into the guide.

Bench Test

Fig 8.0 shows that Tetra and Velocity have a much worse track than any of the previous prototypes with Velocity being the worst, especially at the weld.

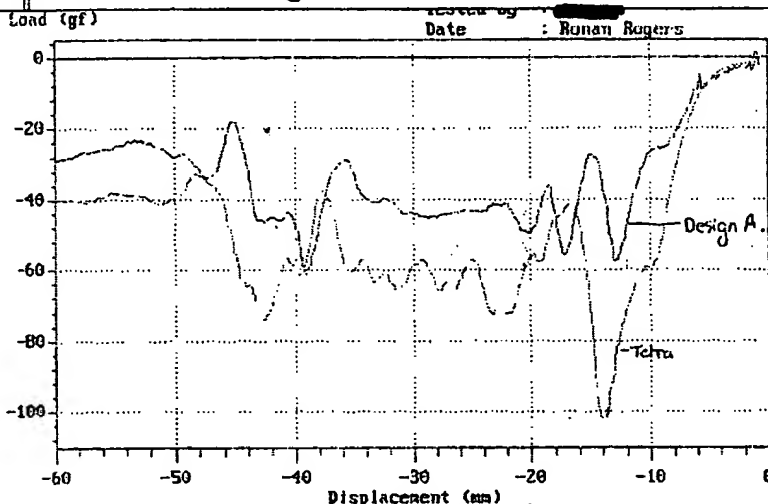


Fig 9.0 Tetra vs Design A

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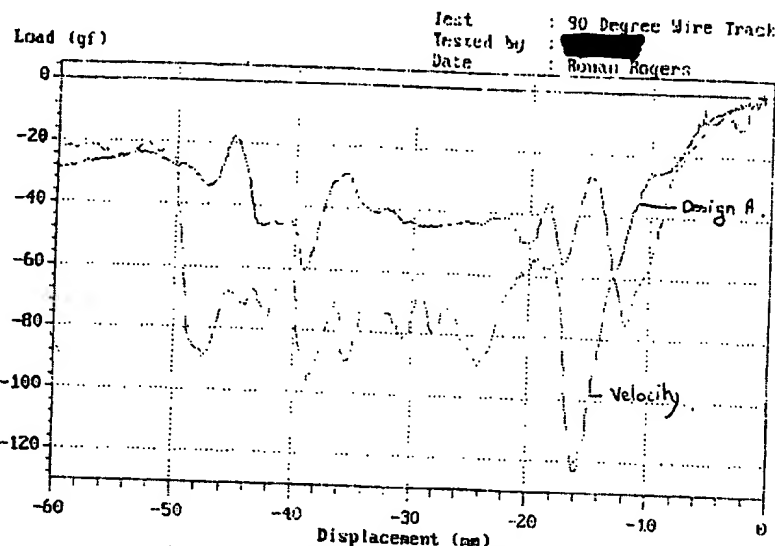


Fig 10.0 Velocity vs Design A.

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Conclusions

The following are some of the conclusions arising from the bench testing and animal trial - both results concurred well with each other.

- B2 in its current form performs considerably better in track than Tekra & Velocity (set).
- Of the three designs Design A performed the best - the distal strain relief was evident.
- The PE inner on Design B+C had some effect on reducing the proximal hinge.
- The hip attach on design B was not noticeable.

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Witness

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Roman Rogers

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